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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,871	09/18/2003	Jean-Pascal Zambaux	ATMI-657	6762
23448 7590 05/10/2007 INTELLECTUAL PROPERTY / TECHNOLOGY LAW PO BOX 14329 RESEARCH TRIANGLE PARK, NC 27709			EXAMINER DEAK, LESLIE R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 05/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/665,871	ZAMBAUX, JEAN-PASCAL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55-62 is/are allowed.
- 6) ☒ Claim(s) 9, 10, 12-29 and 31-54 is/are rejected.
- 7) ☒ Claim(s) 11, 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicants argue that since the method claimed by applicant comprises all the limitations of the claimed product, the claims should be rejoined for examination.

Examiner agrees with applicant's argument, and method claims 55-62 are hereby rejoined for prosecution

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 13 November 2006 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 9, 10, 12, 13, 17-29, 31-34, 36-45, 47-54 are rejected under 35

U.S.C. 102(b) as being anticipated by US 5,122,129 to Olson et al.

In the specification and figures, Olson discloses the apparatus as claimed by applicant. With regard to claims 9, 17, 18, 21, 27, Olson discloses a sampler device designed to preserve the integrity of the sample collected. The apparatus comprises a needle-shaped hollow connector or delivery tube 20 that passes fluids therethrough, an inlet end 13 and an outlet end 21, wherein the inlet end 13 may comprise a threaded connector 19 that connects to container 33 via tube 36 (see FIGS 1, 2, 4, column 6). The outlet end 21 has an aperture to allow fluids to exit into container 23 (see column 7, lines 1-35). The connector comprises a membrane or drip boot 22 (see FIG 4). Absent the disclosure that the drip boot or membrane comprises a vacuum, there is gas inherently contained within the membrane. Furthermore, Olson teaches that the entire assembly is sterile (see column 1, lines 5-12, column 2, lines 20-25) to prevent contamination of the sample obtained through the connector 21, indicating that the gas within the membrane is sterile.

Applicant further claims that the connector comprises **one of** i) a particular pressure of the gas in the membrane, ii) a partial slit in the membrane, iii) a latch between the container and the connector, or iv) a threaded connection between the connector and the container.

With regard to applicant's recitation of the specific pressure of the gas in the chamber, such as "greater than about 1 atm," it is the position of the examiner that "greater than about" 1 atm may include 1 atm, since "about 1atm" may include 0.9 atm.

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(See also claims 12, 13, 31, 32, 49, 52, 54.) Furthermore, due to daily barometric fluctuations in atmospheric pressure, a membrane filled with gas at about 1 atm on a day with low barometric pressure may increase to "greater than about 1 atm" on a day with high barometric pressure. As such, the Olson device meets the limitation of the claims.

With regard to claims 10 and 29, it is the position of the examiner that gas, comprising atmospheric air, is contained within the chamber disclosed by Olson, since Olson does not disclose the chamber as comprising a vacuum. Since atmospheric air comprises a mixture of oxygen and nitrogen, the disclosure meets the limitations of the claims.

With regard to claims 14-15 and 33-35, Olson is silent with regard to the size of the membrane. However, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A).

With regard to claims 19, 20, 51 Olson illustrates a needle-shaped cannula 21 as the connector and a flexible bag 33 as the container (see FIGS 1, 4).

With regard to claim 22, Olson discloses and illustrates that the outlet end of the connector 21 may engage a conventional vacuum tube 23 for receiving fluids through the connector (see FIGS 1, 6, column 7, lines 1-37).

With regard to claims 23-26, Olson discloses that the device may be used to collect blood, which includes whole blood and various blood components, meeting the limitations of the claims (see column 6, lines 18-25).

With regard to claim 28, it has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See MPEP 2144.04(VI)(B).

With regard to claim 44, Olson specifically discloses a kit with the claimed device including packaging materials (see FIG 8, column 5, lines 19-23). Olson does not disclose instructions or indicia on or inside the packaging material. However, applicant has not disclosed or claimed any functional relationship between the components in the kit and the printed matter. The lack of a functional relationship between the kit components and the kit render the instantly claimed kit unpatentable over the prior art of record. See In re Ngai, 70 USPQ2d 1862 (Fed. Cir. 2004). In the instant case, the printed matter, although it may recite a method of using the kit, does not depend on the kit, and the use of the kit does not depend on the printed matter. Therefore, the Olson disclosure meets the limitations of the claims.

With regard to claim 45, Olson discloses a fluid 34 within container 33 (see FIG 1).

With regard to claims 47 and 50, Olson illustrates a threaded connection 19/30 between the connector and the container via tube 36 (see FIGS 3, 4). Examiner interprets applicant's claim drawn to a latch between the container and connector to be a broad recitation of the threaded connection pointed out above.

With regard to claim 48, Olson illustrates the hollow connector 21 as a piercing element (see FIG 4).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9, 10, 12-26, 35, 44, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,122,129 to Olson et al in view of US 6,391,014 to Silverman.

In the specification and figures, Olson discloses the apparatus substantially claimed by applicant. With regard to claims 9, 17, 18, 21, 27, Olson discloses a sampler device designed to preserve the integrity of the sample collected. The apparatus comprises a needle-shaped hollow connector or delivery tube 20 that passes fluids therethrough, an inlet end 13 and an outlet end 21, wherein the inlet end 13 may comprise a threaded connector 19 that connects to container 33 via tube 36 (see FIGS 1, 2, 4, column 6). The outlet end 21 has an aperture to allow fluids to exit into container 23 (see column 7, lines 1-35). The connector comprises a membrane or drip boot 22 (see FIG 4). Absent the disclosure that the drip boot or membrane comprises a vacuum, there is gas inherently contained within the membrane. Furthermore, Olson teaches that the entire assembly is sterile (see column 1, lines 5-12, column 2, lines 20-25) to

prevent contamination of the sample obtained through the connector 21, indicating that the gas within the membrane is sterile.

Applicant further claims that the connector comprises **one of** i) a particular pressure of the gas in the membrane, ii) a partial slit in the membrane, iii) a latch between the container and the connector, or iv) a threaded connection between the connector and the container.

Olson fails to disclose a membrane with a partial slit through the interior thereof. Silverman discloses a container with a diaphragm with a partial slit therethrough (see FIGS 8a-d) to provide diaphragm integrity while maintaining operator safety and optimize needle and diaphragm versatility (see column 6, lines 5-17). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the membrane disclosed by Olson with a partial slit as disclosed by Silverman in order to maintain diaphragm integrity while maximizing operator safety, as taught by Silverman.

With regard to applicant's recitation of the specific pressure of the gas in the chamber, such as "greater than about 1 atm," it is the position of the examiner that "greater than about" 1 atm may include 1 atm, since "about 1atm" may include 0.9 atm. Furthermore, due to daily barometric fluctuations in atmospheric pressure, a membrane filled with gas at 1 atm on a day with low barometric pressure may increase to "greater than about 1 atm" on a day with high barometric pressure. As such, the Olson device meets the limitation of the claim.



With regard to claim 10, it is the position of the examiner that gas, comprising atmospheric air, is contained within the chamber disclosed by Olson, since Olson does not disclose the chamber as comprising a vacuum. Since atmospheric air comprises a mixture of oxygen and nitrogen, the disclosure meets the limitations of the claims.

With regard to claims 14-15, Olson and Silverman are silent with regard to the size of the membrane. However, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A).

With regard to claims 19, 20, 51 Olson illustrates a needle-shaped cannula 21 as the connector and a flexible bag 33 as the container (see FIGS 1, 4).

With regard to claim 22, Olson discloses and illustrates that the outlet end of the connector 21 may engage a conventional vacuum tube 23 for receiving fluids through the connector (see FIGS 1, 6, column 7, lines 1-37).

With regard to claims 23-26, Olson discloses that the device may be used to collect blood, which includes whole blood and various blood components, meeting the limitations of the claims (see column 6, lines 18-25).

With regard to claim 44, Olson specifically discloses a kit with the claimed device including packaging materials (see FIG 8, column 5, lines 19-23). Olson does not disclose instructions or indicia on or inside the packaging material. However, applicant has not disclosed or claimed any functional relationship between the components in the

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kit and the printed matter. The lack of a functional relationship between the kit components and the kit render the instantly claimed kit unpatentable over the prior art of record. See In re Ngai, 70 USPQ2d 1862 (Fed. Cir. 2004). In the instant case, the printed matter, although it may recite a method of using the kit, does not depend on the kit, and the use of the kit does not depend on the printed matter. Therefore, the Olson disclosure meets the limitations of the claims.

With regard to claim 45, Olson discloses a fluid 34 within container 33 (see FIG 1).

With regard to claims 47 and 50, Olson illustrates a threaded connection 19/30 between the connector and the container via tube 36 (see FIGS 3, 4). Examiner interprets applicant's claim drawn to a latch between the container and connector to be a broad recitation of the threaded connection pointed out above.

With regard to claim 48, Olson illustrates the hollow connector 21 as a piercing element (see FIG 4).

### ***Allowable Subject Matter***

6. Claims 55-62 are allowed.

7. The following is an examiner's statement of reasons for allowance: The prior art fails to disclose or suggest the method claimed by applicant. In particular, the prior art fails to disclose a method of providing the claimed device, wherein the connector is covered by a membrane with a gas contained therein wherein the gas comprises a

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sufficient pressure to generate a laminar flow along the connector when the connector pierces the membrane, along with the other steps and limitations of the claims.

8. Claims 11 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is an examiner's statement of reasons for indicating allowable subject matter: The prior art fails to disclose or suggest the device claimed by applicant. In particular, the prior art fails to disclose or suggest the connector claimed by applicant with a membrane over the hollow connector creating a chamber with a gas contained therein, wherein the gas has a particular sterility, along with the other steps and limitations of the claims

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

10. The following claim 9, drafted by the examiner and considered to distinguish patentably over the art of record in this application, is hereby presented to applicant for consideration:

An apparatus comprising:

a hollow connector having an interior wall defining a fluid chamber configured for the passage of fluids, wherein the hollow connector comprises an inlet and an outlet

end, wherein the inlet end is configured to engage a container and the outlet end has an aperture therethrough configured for the egress of the fluids from the container; and

a membrane having an interior surface defining a housing chamber that contains the hollow connector and wherein the chamber contains a gas that is essentially sterile,

wherein the apparatus includes at least the following feature:

the gas inside the housing chamber has a pressure sufficient to generate a laminar flow along the connector when the connector pierces the opening when inside the housing chamber.

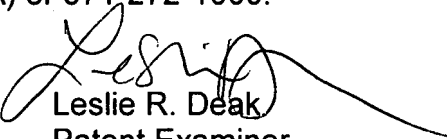
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
9 May 2007